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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/867,753	05/31/2001	Bertram Weiss	SCH-1810	5703

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MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER
MAYES, LAURIE A

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 06/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/867,753	WEISS ET AL.	
	Examiner	Art Unit	
	Laurie Mayes	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-1711* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
4) ☐ Interview Summary (PTO-413) Paper No(s) _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 14 drawn to nucleic acid and a host cell, classified in class 536, subclass 23.1.

II. Claim 2, drawn to a polypeptide, classified in class 530, subclass 350.

III. Claims 3-8, 10 drawn to a method of using a protein as a target substance for the production of an agent for birth control, to treat Alzheimer's disease or to reduce or increase fertility, classified in class 514, subclass 2.

IV. Claims 9 and 11-12 drawn to a method of using a nucleic acid molecule to identify agents that modulate PEM, classified in class 435, subclass 7.1.

V. Claim 13, drawn to a method of diagnosing fertility, classified in class 436, subclass 906.

VI. Claim 15, drawn to a human cell that contains a defective PEM gene in at least one allele, classified in class 435, subclass 325.

VII. Claims 16 and 17, drawn to a method of identifying genes that are regulated by the human PEM gene, classified in class 435, subclass 7.21.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different

inventions are isolated polypeptides and nucleic acid constructs comprised of polynucleotides and recombinant host cells. These inventions are structurally unrelated chemical compounds and have different functions and uses. The polypeptides may be used in an assay or may be administered to treat infection while the nucleic acid construct may be used to encode a peptide.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because a human PEM protein is used in the method of Group III of treating Alzheimer's disease; a nucleic acid is not used to treat the disease. Rather, the nucleic acid in Group I has a different purpose of encoding a protein.

Inventions I and IV and I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid molecule could be used to encode a protein rather than in a method of identifying agents that modulate PEM or in a method of diagnosing fertility.

Inventions I and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the nucleic acid molecule in Group I may be used to

recombinantly encode a protein while the cell in Group VI may be found naturally occurring in nature and have a different biological role in the human body.

Inventions I and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because a human PEM gene is used in the method of Group VI of identifying genes that are regulated by the human PEM gene; a nucleic acid is not used to identify genes that are regulated by the human PEM gene. Rather, the nucleic acid in Group I has a different purpose of encoding a protein.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide could be used in methods other than a method of using a protein as a target substance for the production of an agent for birth control, to treat Alzheimer's disease or to reduce or increase fertility, such as in an assay.

Inventions II and IV and II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide is not used in the method of

identifying agents that modulate PEM for the treatment and/ or diagnosis of Alzheimer's disease or infertility.

Inventions II and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because a human PEM gene of Group V may be used to express hereditary information while the protein in Group II may be used for a different use as in an assay.

Inventions II and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because a human PEM gene is used in the method of Group VI of a method of identifying genes that are regulated by the human PEM gene; a protein is not used to identify genes that are regulated by the human PEM gene. Rather, the protein in Group II may be used for a different use as in an assay.

Inventions III and IV, III and V and IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the methods have different functions as the method of Group III uses a target substance for the production of an agent for birth control, to treat Alzheimer's disease, the method of Group IV is for the identification agents

that modulate PEM for the treatment and/ or diagnosis of Alzheimer's disease and the method of Group V is to diagnose infertility.

Inventions III and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the method of Group III uses a protein, not a human cell that contains a defective PEM gene in at least one allele.

Inventions III and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the method of Group III uses a protein as a target substance for the production of an agent for birth control, to treat Alzheimer's disease or to reduce or increase fertility while the method of Group VI uses transcriptor analysis or proteome analysis for identifying genes that are regulated by the human PEM gene.

Inventions IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the cell may be found naturally occurring in nature and have a natural, biological role while interacting with other cells in the human body which is a materially different process than as a method of identifying agents that modulate PEM for the treatment and/ or diagnosis of Alzheimer's disease or infertility.

Inventions IV and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the method of Group IV uses a protein as a method of identifying agents that modulate PEM for the treatment and/ or diagnosis of Alzheimer's disease or infertility while the method of Group VI uses transcriptor analysis or proteome analysis for identifying genes that are regulated by the human PEM gene.

Inventions VI and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the cell may be found naturally occurring in nature and have a natural, biological role while interacting with other cells in the human body which is a materially different process than as a method of identifying genes that are regulated by the human PEM gene.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and searches required for each, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

A telephone call was made to Anthony Zelano on June 24, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Mayes whose telephone number is (703) 605-1208. The examiner can normally be reached on Monday through Friday from 9 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

L. Mayes

Laurie Mayes
Patent Examiner
Art Unit 1653
June 24, 2003

Christopher S. F. Low

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600